

Summary of Changes in AEATF-II Governing Document of 13 Feb 08

Throughout the document, occurrences of “monitoring unit”, “MU”, or other variations of this term have been changed to “monitoring event” or “ME”.

A few changes of primary interest to ethics reviewers have been made on pp. 31-36, in the discussion of how language differences will be addressed.

Pages 18-20 are substantially different from the previous version, although the first two paragraphs are unchanged. The full text of the deleted passage appears on pp. 195-197.

On pp. 58-66, Section 16, formerly entitled “AEATF-II Program Design”, has been re-titled “Monitoring Event Selection” and substantially revised. This is the generalized discussion of the statistical design for the AEATF-II monitoring program. Many deleted passages are complete in the margins of the “track-changes” version; other longer deleted passages appear on pp. 197-203.

Section 23 (pp. 72-74) entitled “Evaluation of Data Adequacy for Completed BHED™ Scenarios”, has been revised. Deleted text in the margin is shown completely on pp. 203-204.

Appendices A, B, D, F, and G are unchanged. The only change in Appendix C is the substitution of “ME” for “MU” in all occurrences. Appendix E: “Designing Monitoring Events to Predict Future Exposure” has been substantially revised.